

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ALLERGAN, INC.,	§ § § § §
Plaintiff,	§ § § § §
v.	§ §
SANDOZ INC.	§ § CASE NO. 2:09-CV-97
ALCON LABORATORIES, INC., ET AL.	§ CASE NO. 2:09-CV-348
APOTEX, INC., ET AL.	§ CASE NO. 2:09-CV-200
WATSON LABORATORIES, INC.	§ CASE NO. 2:09-CV-344

MEMORANDUM OPINION AND ORDER

I. Introduction

Before the Court is the Amended Motion to Modify the Injunction filed by Defendants Sandoz Inc., Alcon Laboratories, Inc., Alcon Research, Ltd., Alcon, Inc., and Falcon Pharmaceuticals, Ltd. (collectively, “Sandoz”). (Dkt. No. 258.) Defendants Apotex Inc. and Apotex Corp. join in the first and second arguments of Sandoz’s Motion. (Dkt. No. 289.) After considering the parties’ written submissions, the Court **DENIES** Defendants’ Motion.

II. Facts

This Hatch-Waxman case began in April 2009 when Allergan filed suit against Sandoz after receiving a notice from Sandoz that Sandoz had filed an Abbreviated New Drug Application (ANDA) with the FDA seeking approval of a generic version of Combigan®. Allergan asserted infringement of four of its Orange Book-listed patents for Combigan®: U.S. Patent Nos. 7,320,976 (“the ’796 patent”); 7,030,149 (“the ’149 patent”); 7,323,463 (“the ’463 patent”); and 7,642,258

(“the ’258 patent”). The ’258, ’976, and ’149 patents expire on April 19, 2022 and the ’463 patent expires on January 19, 2023.

Shortly before trial, Sandoz, along with the other defendants, filed a stipulation of infringement that the products described in their respective ANDAs “meet[] all of the limitations of claim 4 of U.S. Patent No. 7,030,149, claim 1 of U.S. Patent No. 7,320,976, claims 1-6 of U.S. Patent No. 7,323,463, and claims 1-9 of U.S. Patent No. 7,642,258 pursuant to 35 U.S.C. 271(e)(2)(A),” and therefore the products and their use would infringe. (Dkt. No. 234.) This Court conducted a four day bench trial in August of 2011, presided over by Judge T. John Ward, and concluded that Defendants’ proposed generic version of Combigan® infringed all four patents-in-suit, based on the stipulations, and that the patents had not been shown to be invalid. (Dkt. No. 259 at 101.) As required by 35 U.S.C. 271(e)(2)(A), this Court then entered judgment prohibiting approval of Defendants’ ANDAs until the latest of the expiration dates of the ’149, ’976, ’463, and ’258 patents and enjoining Defendants from making, using, offering to sell, or selling the products described in their respective ANDAs for the same period. (Dkt. No. 260.)

Defendants appealed and the Federal Circuit issued its opinion on May 1, 2013, affirming in part and reversing in part. The Federal Circuit found claim 4 of the ’149 patent valid, found claims 1-6 of the ’463 patent invalid as obvious, and declined to rule on the validity of the ’976 and ’258 patents, explaining that “[t]he ’258, ’976, and ’149 patents each expire on April 19, 2022. Because we conclude that claim 4 of the ’149 patent is not invalid, the Appellants will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the ’258 and ’976 patents.” *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1294 n.2 (Fed. Cir. 2013). In a motion for rehearing *en banc*, the Defendants challenged the panel’s conclusion that it need not

rule on the validity of the '976 and '258 patents. Rehearing was subsequently denied. The Federal Circuit issued its final opinion and mandate on September 16, 2013.

Sandoz files the present motion, pursuant to Rule 60, asking this Court to (1) modify the permanent injunction to reflect the Federal Circuit holding that claims 1-6 of the '463 patent are invalid, (2) extend the invalidity finding of the '463 patent to the '258 and '976 patents, and (3) make a determination that Sandoz's amended ANDA does not infringe claim 4 of the '149 patent. Allergan opposes this request, contending that this is not the type of situation for relief from judgment contemplated by Rule 60; instead, this is an attempt to re-litigate the case. After considering the written submissions from both sides, the Court finds that Allergan has the better argument, and Sandoz's motion should be denied.

III. Applicable Law

Sandoz moves for a modification of judgment under Rule 60(b)(5) and (6). Rule 60(b)(5) provides that a court may relieve a party from a final judgment when "applying it prospectively is no longer equitable." Therefore, a party seeking modification "bears the burden of establishing that a significant change in circumstances warrants revision of the [injunction]." *Rufo v. Inmates of Suffolk County Jail*, 502 U.S. 367, 383, 112 S.Ct. 748 (1992); *ICEE Distributors, Inc. v. J&J Snack Foods Corp.*, 445 F.3d 841, 850 (5th Cir. 2006) ("Modification of an injunction is appropriate when the legal or factual circumstances justifying the injunction have changed.") (citations omitted).

Although such a significant change in circumstances does not have to be entirely unforeseen or unforeseeable, a modification is not appropriate where a party relies upon events that were anticipated at the time that injunction was entered. *Rufo*, at 385. Instead, relief is more properly available in the instance where a change in circumstance is beyond the defendants'

control. *Frew v. Hawkins*, 401 F. Supp. 2d. 619, 629 (E.D. Tex. 2005). Once the movant has satisfied its burden to establish a change in circumstances sufficient to warrant modification, the district court should determine whether the proposed modification is suitably tailored to address the change. *Rufo*, at 391.

IV. Analysis

Before taking up modification of the injunction, the Court first considers the requests to (a) extend the invalidity finding of the '463 patent to the '258 and '976 patents, and (b) make a determination that Sandoz's amended ANDA does not infringe claim 4 of the '149 patent.

a. Validity of the '258 and '976 patents

As the premise in its motion, Sandoz asserts that the Federal Circuit's decision and the denial of Sandoz's petition for rehearing leaves an open issue on the validity of the '258 and '976 patents which is appropriate for this Court to resolve. This premise is rooted in the flawed proposition that the case has been remanded to this Court for further proceedings. In contrast to this assertion, the Federal Circuit's decision was clear. Judgment was affirmed-in-part and denied-in-part, and no further action is required. The Federal Circuit did not remand this case to the District Court, and without such direction, this Court has no continuing jurisdiction to take the action Sandoz requests.

Nevertheless, Sandoz moves this Court to take the appellate court's determination of invalidity as to the '463 patent and extend it to the claims of two other patents. This is something the Federal Circuit specifically declined to reach. It should also be noted that Sandoz advanced the same argument in its petition for rehearing *en banc* and such rehearing was denied. Consequently, without a specific remand from the court of appeals on this issue, the district court's validity judgment on the '258 and '976 patents remains undisturbed. This Court is not free to alter or

extend the judgment of the circuit court unless and only to the extent the circuit court so directs in its opinion.

Additionally, reconsideration of the Court's prior validity judgment is not appropriate under a Rule 60 analysis. Whether the obviousness holding constitutes a significant change of circumstances or not, the obviousness holding by the circuit court does not automatically give this Court cause to reconsider other patents previously adjudicated as valid and not reached by the Federal Circuit. As each claim is independent of the other, distinct patents do not rise or fall together, and Sandoz has provided no authority to the contrary. As a result, the obviousness holding of the Federal Circuit is limited, as it clearly set forth, to the '463 patent. Such a ruling is not the type of changed circumstance sufficiently significant to warrant a modification to the validity of the '258 and '976 patents.

b. Sandoz's amended ANDA

As another basis for relief, Sandoz petitions the Court for a ruling that its amended ANDA, which was submitted after the Federal Circuit's ruling, does not infringe claim 4 of the '149 patent. The amendment purports to carve out an infringing element in an attempt to escape the judgment imposed by Judge Ward which was affirmed on appeal. Sandoz argues that the amended label has been indicated as acceptable by the FDA.¹ Therefore, it asserts, the Court should deem this design-around to not infringe the '149 patent and the present injunction should be modified to permit Sandoz to launch this new version of its product. (Dkt. No. 300.)

A party seeking modification of a judgment under Rule 60 "bears the burden of establishing that a significant change in circumstances warrants revision of the [judgment]." *Rufo*,

¹ Much of Sandoz's briefing is dedicated to explaining how its amended ANDA proposes a formula that is only directed to ocular hypertension patents, which stops short of satisfying a step in the asserted claim. However, this Court offers no opinion on the merits of Sandoz's non-infringement argument at this time.

502 U.S. at 383; *ICEE*, 445 F.3d at 850. Sandoz has not alleged a single change in its circumstances that was brought about by new or unforeseen conditions. The only changed circumstance that is relevant to Sandoz's non-infringement argument is the ANDA that it voluntarily amended after the Federal Circuit affirmed validity of the '149 patent. This was an intentional act that cannot be fairly characterized as unforeseen or unexpected. Sandoz's argument that there were forty possible validity-infringement outcomes in this case is unpersuasive. Every patent case involving disputes as to infringement and validity can inherently result in numerous combinations of infringement/validity that are each entirely foreseeable by the parties involved. The numerosity of the claims alone does not render one outcome from forty possibilities exceptional or unanticipated. Moreover, the changed ANDA occurred entirely through the actions of Sandoz and, by definition, is not beyond the defendant's control. Consequently, this is "not the kind of unforeseen change in circumstances that merits relief from a judgment" under Rule 60(b)(5). *Valentine Sugars, Inc. v. Sudan*, 34 F.3d 320, 321-322 (5th Cir. 1994) ("Appellant not only foresaw the changed conditions, it created them. The district court correctly denied relief from the judgment.").

In addition, the request for a ruling of non-infringement based on the changed ANDA is tantamount to seeking summary judgment premised on new allegations that only came to exist after the final judgment was rendered and affirmed. This Court finds no basis in the law for such relief. Here, Sandoz stipulated to infringement, tried the case on invalidity and lost, and is now trying to change positions to obtain another chance at non-infringement via the modified ANDA. "It is well established that a party 'may not use a Rule 60(b) motion as an occasion to relitigate its case.'" *United States v. Davison*, 509 F. App'x 330, 332 (5th Cir. 2013) (quoting *Gen. Universal Sys. V. Lee*, 379 F.3d 131, 157 (5th Cir. 2004)). In its motion, Sandoz alleged no facts indicating

that the carve-out was “not open to litigation in the former action or that [it] was denied a fair opportunity to make [its] claim or defense in that action.” *Addington v. Farmer’s Elevator Mut. Ins. Co.*, 650 F.2d 663, 668 (5th Cir. 1981). Instead, the facts reveal that Sandoz fully litigated the merits of its invalidity case before this Court, “and then, displeased with the outcome, [now seeks] to escape the consequences of this choice by shifting to a different course after the fact.” *Paul Revere Variable Annuity Ins. Co. v. Zang*, 248 F.3d 1, 8 (1st Cir. 2001). Sandoz must live with the consequences of the choices it freely made, and the calculated decisions it strategically reached in the course of prior litigation. *Id.* Such facts are far removed from the type of inequity that warrants relief under Rule 60(b)(5).

c. Modification of the permanent injunction

In light of the Federal Circuit’s reversal-in-part, Sandoz moves the Court to shorten the injunction period to the expiration date of the ’149, ’976, and ’258 patents—April 19, 2022. Allergan responds that the injunction is clear on its face; defendants are enjoined until “after the latest of the expiration dates of the ’149, ’976, ’463, and ’258 patents, plus any exclusivities afforded under the statute.” (Dkt. No. 260.) This Court agrees. The Federal Circuit’s obviousness finding of claims 1-6 of the ’463 patent invalidates those claims, the effect of which is retrospective. Claims 1-6 of the ’463 are treated as if they never existed, and by extension, they have no expiration date. Accordingly, based on a plain reading of the language in the injunction, no modification is necessary or proper.

V. Conclusion

For the foregoing reasons, the Court finds that Sandoz has failed to meet its burden to establish a significant change in circumstances which warrants relief under Rule 60(b)(5). It is also apparent to the Court that Sandoz does not meaningfully move to modify the injunction under Rule

60(b)(6) as a separate ground for relief. Sandoz's Amended Motion to Modify the Injunction (Dkt. No. 258) is hereby **DENIED** in all respects.

So Ordered and Signed on this

Dec 2, 2013



RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE